JAN 6 2011

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	T.A.G. Medical Products Corporation, Ltd. D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: 972-3-647-4840
	Contact Person:	Dan Moor
	Date:	May 30, 2010
2.	***Device & Classification Name:***	Smooth or threaded metallic bone fixation fastener, class II device (product code MBI). *GrappLR™* and *GrappLR™ Extender*
3.	***Predicate Devices:***	K070167- Smith & Nephew EndoButton Direct K081098- Smith & Nephew EndoButton Continuous Loop K070780- ConMed Linvatec XO Button
4.	***Description:***	The GrappLR™ suspension fixation device is a single-use, titanium implant used for fixation of soft tissue to bone. The GrappLR™ has two configurations: One has a Continuous Loop, made of ultra high molecular weight polyethylene, offered in several sizes to accommodate various bone tunnel lengths. The second configuration does not have a loop, and enables custom loop lengths to be tied using an appropriate material (not included). Both of these configurations have a Lead Suture. The GrappLR Extender™ is a single-use, titanium implant used for providing additional button width and length to the GrappLR™.
5.	***Intended Use:***	The GrappLR™ and GrappLR™ Extender are intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or assist in reconstruction surgeries and to assist in the management of reconstructive surgeries.
6.	***Comparison of Technological Characteristics:***	With respect to its indication for use, the GrappLR™ and GrappLR™ Extender is substantially equivalent to its predicate devices in that it intended for the same clinical purpose. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products Corporation, Ltd. believes that its device is safe and effective because it performs the same function in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

T.A.G. Medical Products Corporation Ltd.
c/o Mr. George Hattub
Regulatory Consultant
291 Hillside Avenue
Somerset, MA 02726

JAN 6 2011

Re: K101616
Trade/Device Name: GrappLR and GrappLR Extender
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: December 21, 2010
Received: December 29, 2010

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: GrappLR™ and GrappLR™ Extender

Indications For Use: The GrappLR™ and GrappLR™ Extender are intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or assist in reconstruction surgeries and to assist in the management of reconstructive surgeries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101616